

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 98,714)

In re Application of:)	
)	
David Baunoch, et al.)	
)	Group Art Unit: 1623
Serial No.: 09/212,367)	
)	Examiner: W. Beisner
Filed: December 15, 1998)	
)	
For: METHOD AND APPARATUS FOR)	
AUTOMATED REPROCESSING OF)	
TISSUE SAMPLES)	

Commissioner for Patents
 Washington, DC 20231

DECLARATION OF THOMAS G. KENNEDY
PURSUANT TO 37 C.F.R. § 1.132

I, Thomas G. Kennedy, declare as follows:

1. I have been employed by Ventana Medical Systems, Inc. since October 1998. From October 1998 to 1999, I served as both the sales manager for tissue processors and the eastern region service manager for Ventana Medical Systems, Inc.'s entire product line. In 1999, I became the Eastern Region Service Manager for Ventana Medical Systems, Inc.'s entire product line. And, in July 2001, I became the U.S./Canada National Service Manager for Ventana Medical Systems, Inc.'s entire product line.

2. Prior to working at Ventana Medical Systems, Inc., I worked for RMC, Inc. from July 1992 – October 1998. In July 1992, I held the position of National Service Manager for RMC, Inc. In approximately 1995-1996, I became Director of Service for RMC, Inc.'s tissue processors, rotary microtomes and electron microscopy microtomes. In the summer of 1998, I

became the Director of Sales for tissue processors and rotary microtomes and Director of Service for tissue processors, rotary microtomes and electron microscopy microtomes.

3. Prior to working at RMC, Inc., I worked at Fisher/Instrumentation Laboratory from May 1986 – July 1992. From May 1986 – March 1989, I held the position of Field Service Engineer at Fisher/Instrumentation Laboratory. From March 1989 – March 1992, I held the position of Histology product support manager. From March 1992 – July 1992, I held the position of project manager, responsible for inter-company decisions for the sale of the histology tissue processor product line.

4. Based on my experience in the field of tissue processing and in speaking with histologists, approximately 5% of processed tissues needs to be reprocessed. There are several reasons for reprocessing a tissue sample. One reason is that if the tissue processing machine fails at any point in the process, the tissue needs to be reprocessed in order to process the tissue again. Another reason is if the tissue sample is too fatty and does not process well, the tissue sample should be reprocessed. Still another reason is that, in research settings, one may wish to rehydrate the tissue thereby requiring the reprocessing of the sample.

5. The time required to entirely reprocess a tissue sample (embedding, clearant, dehydration, and fixation) is approximately 6 hours (approximately 1½ hours per step). Without automated reprocessing, a histologist must perform the necessary reprocessing steps manually.

6. Using automated reprocessing of tissue samples may allow for quicker evaluation of samples. For example, if the processing machine failed during processing, the histologist would identify the error. The samples would then have to be reprocessed. With an automated reprocessing machine, the samples could be reprocessed overnight and then be processed during the next day. Without automated reprocessing, the manual reprocessing would typically occur

the following day during the histologists ordinary shift. This delay in reprocessing would lead to a delay in the overall analysis of the sample.

7. Automated processing of tissue sample has been performed since the mid-1950s.

8. To my knowledge, Ventana Medical Systems was the first to develop automated reprocessing of tissue samples.

9. Thermo Shandon, Inc. (part of Thermo Electron Corp.) now offers the Pathcentre product which includes "reverse processing capability." See Exhibit A.

10. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of the Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Further the declarant sayeth not.

Respectfully submitted,

1-24-02
Date

Thomas G. Kennedy
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